



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/664,601

09/18/2003

Weenna Bucay-Couto

03-278US1

3626

27774 7590 07/08/2010

MAYER & WILLIAMS PC  
251 NORTH AVENUE WEST  
2ND FLOOR  
WESTFIELD, NJ 07090

EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

07/08/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,601	<b>Applicant(s)</b> BUCAY-COUTO ET AL.	
	<b>Examiner</b> TIMOTHY E. BETTON	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14 and 16-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 16-21, and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicants' response filed on 30 March 2010 has been acknowledged and duly made of record.

#### *Response to Arguments*

Rejection under 35 U.S.C. § 103(a) Seo and Desai in view of Gentz, Cortese, and Glajch are averred by applicants because of allegedly failing to teach a chemical ablation agent. Further, it does not teach *a first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. In fact, the words "crosslink," "crosslinking," "crosslinked" or "crosslinkable" are found nowhere in Seo et al., Desai, Gentz, Cortese, and Glajch.*

Also, as a matter of first importance the amendment to claim 1 to delete *tissue* and insert *dosage form* has not been clearly elucidated in the instant claim set. Upon a search in the specification to extract this limitation drawn to *[a]n injectable or injectible dosage form for producing specific necrosis of tissue that comes into contact with the dosage form comprising [...]*, is unclear in grammatical representation and also appears to have no support in the specification.

Further, applicants' assert that the secondary references, Hauschild et al., Escandon et al., and Unger et al., employed in the previous rejection also additionally failed to adequately address *a first and second biodisintegrable polymers, wherein at least one of said first and second biodisintegrable polymers is crosslinked at an outer surface of the dosage form. In fact,*

Art Unit: 1617

*the words "crosslink," "crosslinking," "crosslinked" or "crosslinkable" are found nowhere in Hauschild et al., Escandon et al., and Unger et al.*

Applicants' arguments are considered but are not found persuasive because there is no clear support in the specification for the amendment to claims 1 and 37. In other words, the limitation as disclosed drawn to *a biodegradable binder comprises first and second biodegradable polymers, wherein at least one of said first and second biodegradable polymers is crosslinked at an outer surface of the dosage form* is nowhere taught or clearly defined in the current specification.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Status of the Claims***

Claims 1-4, 6-14, 16-21, and 33-38 are pending further prosecution on the merits. Claims 22-32 are withdrawn from further consideration. Claims 5 and 15 are cancelled.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-14, 16-21, and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (USPN 6,277,391 B1) and Desai et al (USPGPUB 2003/0130575 A1) in view of Gentz et al. (USPN 6,869,927 B1), Cortese et al. (USPGPUB 2002/0010150 A1), and Glajch et al. (USPN 5,147,631).

Seo et al. teach a composition and method for treating diseases and disorders of the prostate such as prostatitis, benign prostatic hypertrophy, and prostate carcinoma. ***The prostate is treated by intraprostatic injection of a biodegradable sustained release formulation. By injecting the treatment substance directly into the prostate, improved treatment results are obtained with a much lower treatment substance dosage.*** Additionally, by incorporating the treatment substance into a biodegradable sustained release formulation, the need for frequent repetition of injections is eliminated (abstract only).

Accordingly, Seo et al. teach a step which discloses the exact dimension of particles size as disclosed in instant claim 6 (see column 16, lines 19 and 20). The teachings of Seo et al. are

Art Unit: 1617

directed to a treatment for prostatic cancers *inter alia*, principally, which reasonably is encompassed by the limitations of the current invention. Instant claim 1 discloses *comprising* language which makes the claim broad and not exclusive. Therefore, the teachings and modifications of Desai and Seo et al. reasonably extend in obviousness over the claimed invention.

Seo et al. teach at column 3 at line 26 that in order for the therapeutically effective substance to be viable it *will* be combined with biodegradable polymer.

Seo et al. does not teach the limitations drawn to a specifically named biodisintegrable polymer.

However, Desai et al. teach methods and apparatus for body tissue treatment using laser energy and electromagnetic radiation, and more specifically to methods and apparatus wherein laser energy and electromagnetic radiation are delivered to target tissue for controlled heating of tissue and for enhancing localized tissue ***necrosis*** thermal energy can be generated from Laser, microwave, electromagnetic radiation, RF and ultrasound or combinations of energy sources [0003] [0005].

Desai et al. teach solid and semi-solid dosage forms [paragraphs, 68, 9<sup>th</sup> line from bottom; (col. 1, last 2 lines from bottom)].

Specifically, Desai et al. teach a method of Laser treatment specifically for a prostate for achieving prostate ablation for treatment of BPH and prostate cancer, bladder cancer and lower urinary tract [...][0095].

However, Gentz et al. reasonably encompasses the limitations disclosed in claims 9-20 by teaching [...] liquid injectable formulations of keratinocyte growth factor-2 (KGF-2) and

Art Unit: 1617

derivatives thereof (column 1, lines 19-24, and column 4, line 11-67), comprising KGF-2 polypeptides and sodium chloride as a tonicifier at a concentration of from about 0 to about 150 mM (NaCl) (column 4, line 34). Sodium chloride of about 150 mM is reasonably construed to serve as a chemical ablation agent in amount effective to cause tissue necrosis and to reasonably serve as a **biodisintegrable viscosity adjusting agent** in an amount effective to render the formulation highly viscous (see instant specification, page 3, paragraph 0019, line 1 to paragraph 0020, line 2; and page 5, paragraph 0026). Gentz et al. teach that the KGF-2 to be used for therapeutic administration may be sterile and that sterility is readily accomplished by filtration through sterile filtration membranes (column 14, lines 33-35). Sodium chloride is reasonably construed to be an osmotic-stress- generating agent in view of applicant's disclosure that "[I]n some embodiments, the ablation agents are osmotic-stress-generating agents, for example, a salt, such as sodium chloride (page 3, paragraph 0020, lines 1-2)." Gentz et al. teach that the formulations may employ "suitable pharmaceutical diluents," including but not limited to, saline, buffered saline, dextrose, water, glycerol, ethanol, and combinations thereof (column 12, lines 29-34). "Suitable pharmaceutical diluents .... and combination thereof is reasonably construed to encompass an amount of water and ethanol suitable for the preparation of a sterile injectable formulation as claimed in the instant application (specification page 5, lines 1-2).. Gentz et al. teach that thickening agents are used to increase the viscosity of the formulation e.g. carboxymethyl cellulose (CMC), hydroxyethyl cellulose (HEC), hydroxypropylmethyl cellulose (HPMC), natrosol, and carbomers (column 2, lines 3-7). Gentz et al. teach examples of etherified cellulose to include alkyl celluloses e.g. methylcellulose, hydroxyethyl cellulose, hydroxyl propyl cellulose, hydroxyl propyl methylcellulose, and the like (column 9, lines 5-9).

Art Unit: 1617

Gentz et al. teach that when thickening agents are added to the injectable formulations, salts and buffering agents may be added or removed from the formulation for optimal stability (column 9, second paragraph, lines 1-3). Gentz et al. teach that gelling agents may be added to the injectable formulations, including vinyl polymers, polyoxyethylenepolyoxypropylene copolymers, polysaccharides, proteins, poly(ethylene oxide), acrylamide polymers and derivatives and salts thereof; useful polysaccharides include cellulose derivatives, glycosaminoglycans, agar, pectin, alginic acid, dextran, starch, and chitosan (column 10, lines 19-51 ). Based on this teaching, ionically cross-linkable polymers such as alginate polymer are reasonably within the capabilities of someone of skill in the art.

Thus, based on the teaching of Gentz et al., someone of skill in the art would have been motivated to create the instant claimed inventive concept. Thus, someone of skill in the art at the time the instant claimed invention was made to create the instant invention with a reasonable predictability in view of the general knowledge of the state of the art.

Gentz et al. does not teach solid and semi-solid formulations. However, the one of skill would readily incorporate the teachings of Cortese to reasonably provide further motivation to combine based upon characterization optimization of the teachings of Gentz et al. in view of Cortese et al.

Cortese et al. teach cross-linkage of polymers (paragraph 69).

Accordingly, on page 7 under Uses of PA/PO Compositions, Cortese et al. teach embodiments drawn specifically to the administration via injection with a needle (104, last line).



Cortese et al. essentially teach in paragraph 105 embodiments which are reasonably obvious over the claims in the instant invention drawn to solid and semi-solid dosage forms.

Cortese et al. teach prostate surgery (page 14, claim 39, line 5). Thus, the polyacids of Cortese et al. make the biodegradable binder obvious to be included in the formulation in view of the claimed invention and all elements represented by Cortese et al.

Cortese et al. does not teach an imaging contrast medium or the micron dimensions according to claim 6.

However, Glajch et al. is added to show the general knowledge in the art regarding formulations comprising contrast agents, polymers, and solid particles. Glajch et al. teach ultrasound contrast agents comprising porous particles of an inorganic material having an average particle diameter of about 0.05 to 500 microns and containing entrapped gas or liquid; the inorganic material includes monomeric and polymeric forms of one or more of the following: borates, aluminas, carbonates, silicates, silicas, aluminosilicates, phosphates, and organic or inorganic cationic salts thereof (column 2, lines 11-27). This teaching is reasonably construed to satisfy the "wherein the plurality of solid particles is selected from calcium carbonate particles ..." instant claim limitation. For parenteral use, the particles are preferably about 0.2-10 microns in average diameter (column 2, lines 33-34). Glajch et al. teach that these contrast agents are useful for ultrasound imaging of a body organ system (column 2, lines 66-68).

Based on the teaching of Glajch et al. of ultrasound contrast agents useful for ultrasound imaging of a body organ system, someone of skill in the art would have been motivated to combine the teachings of the above cited references to arrive at the instant

Art Unit: 1617

claimed invention. Thus, someone of skill in the art would have deemed it obvious at the time of the invention was made to create the instant invention with reasonable obviousness.

Desai et al. teach methods and apparatus for body tissue treatment using laser energy and electromagnetic radiation, and more specifically to methods and apparatus wherein laser energy and electromagnetic radiation are delivered to target tissue for controlled heating of tissue and for enhancing localized tissue *necrosis* thermal energy can be generated from Laser, microwave, electromagnetic radiation, RF and ultrasound or combinations of energy sources [0003] [0005].

Desai et al. teach solid and semi-solid dosage forms [paragraphs, 68, 9<sup>th</sup> line from bottom; 91, last 2 lines from bottom].

Specifically, Desai et al. teach a method of Laser treatment specifically for a prostate for achieving prostate ablation for treatment of BPH and prostate cancer, bladder cancer and lower urinary tract [...][0095].

Desai et al. does not teach a weight average particle size between 1 and 100 microns in largest dimension.

Thus, it would have been prima facie obvious to the one of skill at the time of invention to see a reasonable expectation of success via the combining together the teachings of Seo, Gentz, Desai, Cortese and Glajch.

Desai et al. teach embodiments drawn to the necrosis of tissue which suggests and supports obviousness over the claimed invention with the exception of teaching 1 to 100 microns. Seo et al. overlaps the teachings of Desai while teaching the range limitation of claim 6. Gentz et al. reasonably encompasses the teachings drawn to biodegradable binders by disclosing all the essential elements contained within claims 7 and 9-20. The one of skill is

Art Unit: 1617

inclined to recognize the limitation drawn to *encapsulated* as reasonably encompassed by the broadest meaning attributed to the microparticles of Desai et al. reference. Cortese et al. exemplify the teachings of Gentz et al. by expressly teaching a solid/semi-solid formulation. Glajch provides further motivation via the teaching drawn to an imaging contrast agent.

Claims 2-4 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (USPN 6,277,391 B1), and Gentz et al. (USPN 6,869,927 B1) in view of Desai et al (USPGPUB 2003/0130575 A1), Cortese et al. and Glajch et al. (USPN 5,147,631) as applied to claims 1 and 6-21 above, and further in view of Hauschild et al. (USPN 6,905,475), Escandon et al. (USPN 7,015,253) and Unger et al. (USPN 5,733,572; USPN 5,733,572; USPN 6,443,898; USPN 6,123,923).

Hauschild et al. teach a method and surgical instrument for treating prostate tissue including a surgical instrument having a main body, a needle deployment port, a needle, first and second handles and a lockout release mechanism to limit needle extension. Additionally, a kit includes the surgical instrument, together with a cystoscope, and optionally a syringe and reservoir of ethanol. The method includes needle-less injection and visualizing the ethanol injection by delivering both an echogenic agent and ethanol either by needle or needle-less injection or by providing an ultrasonically visible marker near the tip of the ethanol delivery cannula. The method also includes extending the needle transversely of the instrument housing using a link assembly (Abstract)."

In patented claim 1, Hauschild et al., teach a method of injecting a drug into prostate tissue. Column 3, line 30 specifically teaches the use of a surgical instrument: the scope allows visual positioning of the needle port against the urethra adjacent to the lobe of the prostate to be

Art Unit: 1617

treated. The needle is advanced one detent click at a time to place the needle tip in the adenoma. A small volume of an active ingredient such as anhydrous alcohol is slowly injected into the tissue. The urethral lumen may be continuously irrigated while the ethanol is being administered. The embodiment suggests a process similar to a manner of necrotizing compromised tissue. However, in other aspects of the invention in Figures 9 and 10, column 6, lines 35-40, there is a disclosure of transurethral ablation. Furthermore, in column 1, line 39-57, ablation is initially disclosed but in relation to laser treatments. Additionally, it is disclosed that ablation is associated with the process of surgically damaging prostate tissue. One of ordinary skill in the art would readily recognize that as a result of surgically damaging prostate tissue, there is certain to be necrotizing of said tissue. However, removal or excision of such compromised tissue is not as apparent. The dosage form of the active ingredient as disclosed in a specific embodiment is a sterile semi-solid in consistency, i.e., GELFOAM® Sterile Powder.

In column 10 of Hauschild et al., patented claim 1 is obvious over subject claim 8, which discloses an injection or insertion into the tissue via a jet injector. The referenced patent teaches a surgical instrument disclosed in column 5, lines 49 to 55 similar to the jet injector apparatus disclosed in instant claim 8. In addition, said instrument contains a disclosure as to make the needle more visible on ultrasound and ways to make the fluid delivered more visible which is similar to the disclosure of a contrast agent in instant claim 21.

Escanden et al. teach, "The present invention provides treatment regimens for treating diseased prostate tissue, including the steps of chemically ablating prostate tissue and coadministering an antiandrogen. In some embodiments, injection of ethanol, or an injectable gel comprising ethanol, into prostate tissue, chemically ablates prostate tissue. Steroidal and non-

Art Unit: 1617

steroidal antiandrogens are suitable antiandrogens. One suitable non-steroidal antiandrogen is bicalutamide. The treatment regimen is suitable for treatment of prostate tissue diseases including benign prostatic hyperplasia and prostatic carcinoma. The invention further provides a treatment regimen for treating benign prostatic hyperplasia, including the steps of damaging prostate tissue and coadministering an antiandrogen. Also provided by the present invention is a kit for treating a human male, including a means for necrosing prostate tissue, an antiandrogen drug, and a means for administering the antiandrogen drug. A kit including a first surgical device for delivering a chemoablation fluid to prostate tissue transurethrally, an antiandrogen drug such as bicalutamide, and a second surgical device for administering the antiandrogen drug, is further provided (Abstract)."

Specifically, Escanden et al. is obvious over instant claims 20 and 21 in instant application. In column 5 and 6 of referenced patent, several embodiments of chemoablation are cited. In one embodiment, the present invention provides a treatment regimen for treating diseased prostate tissue. The treatment regimen includes the steps of chemically ablating prostate tissue sufficiently to elicit a reparative process in the absence of further treatment; and coadministering a therapeutically effective amount of an antiandrogen.

"As used throughout this specification, the terms "ablate," "ablation" or "ablating" of tissue means causing a reduction in tissue mass. One suitable manner of ablating tissue is by causing a decrease in the number of tissue cells. The phrase "chemical ablation" includes processes whereby tissue mass is reduced by action of a chemical or biological agent on the tissue. The size of the prostate is reduced relative to its size prior to treatment by the treatment regimen. The treatment regimen is suitable for treatment of prostate tissue diseases

Art Unit: 1617

including BPH and prostatic carcinoma. One suitable procedure for chemically ablating prostate tissue in accordance with the treatment regimen is by injection of ethanol (absolute alcohol) into the prostate to be treated. Ethanol preferably is injected deeply into prostate tissue through a needle that is positioned transurethrally, such as in the procedure known as transurethral ethanol ablation of the prostate (TEAP). The ablating action of ethanol is due to several processes, including dehydration of cells, coagulation of proteins, and thrombosis of vessels that feed the tissue.”

Column 17, the surgical instrument called a PROSTAJECT is similar in scope to the jet injector as disclosed in instant claim 8. Further, on line 11 the means for necrosing prostate tissue is disclosed. In particular, the ethanol is intended to be used as an ablating or necrosing agent, and the antiandrogen is intended to be coadministered according to any of the treatment regimens described above. The antiandrogens described above are suitable for the combination medicament. Bicalutamide in particular is a suitable non-steroidal antiandrogen (column 18). In column 10, line 11 an additive for enhancing the visibility of the chemoablation fluid may be incorporated via specialized dyes. This similarity is found likewise in instant claim 21, which discloses imaging via contrast agents.

Hauschild et al. do not directly teach specific claims in regard to necrotizing prostate tissue, however a combination of a contrast agent (i.e., visible marker) and an ultrasonic beacon are disclosed within patented claims in order to facilitate detecting and determining amount of agent to specific site of prostate tissue via surgical instrument. Further, referenced patent does not teach an identical model of a jet injector as disclosed in instant claim 8, however the apparatus used is significantly similar in design, operation, and effect.

Escanden et al. does not teach the identical embodiment of contrasting agents as disclosed in instant application. Further Escanden et al does not teach treatment to other body regions except to prostate tissue.

However, the Examiner refers to Unger et al., which discloses a filtration process by which the resultant active ingredient (unfiltered volume) yield a volume of 80-90% of the unfiltered volume. This disclosure reasonably makes the limitations of claims 33-36 obvious based upon the variable range and the comprising language employed.

Unger et al. (6443898) teach microspheres (bead, instant claim 3) that are disclosed to have a semi-solid consistency and are intended for use in a therapeutic drug delivery system [Detailed Description Text (87)].

Unger et al. (6123923) teach the incorporation of a glycolic acid polymer (film-forming material at the surface) so as to maintain stability of dosage form in association with solid matrices [Detailed Description Text (94)]. Further, Unger et al. teach fiber (instant claim 4) as a dosage form directed toward use as a contrast agent (instant claim 21) that is used in conjunction with ultrasound for surgical procedures [Drawing Description Text (10)].

Furthermore, instant claim 2 discloses a dosage form in the shape of a cylinder. The inner space of a needle (injection dosage form) cannula is shaped cylindrically, so as to accommodate various formulations that may be semi-solid within the needle housing, thereby properly addressing said limitation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and devices of Hauschild et al. and Escanden et al. to include administration of a chemical ablation agent/biodisintegrable formulation for

Art Unit: 1617

insertion or injection in view of the motivation of Unger et al. as disclosed above. There is substantial documentation in the prior art, which suggests the motivation via obviousness to combine the teachings of Hauschild et al. and Escanden et al. by reasonable explanation of producing an effective chemoablative/ therapeutic drug delivery system. It would instantly be obvious to one of ordinary skill in the art to see the motivation of Unger et al. in regard to disclosures/data supporting detailed explanations to purport the optimal scope of the subject invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***



Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627